

CRT-47

Two-Year Outcomes Following Platinum Chromium Everolimus-Eluting Stent Implantation in Small Vessel Lesions in Japan

Shigeru Saito,¹ Masashi Iwabuchi,² Toshiya Muramatsu,³ Atsuo Namiki,⁴ Toshiyuki Matsumura,⁵ Keiichi Igarashi,⁶ Junji Yajima,⁷ Shigeru Nakamura,⁸ Dominic J Allocco,⁹ Keith D Dawkins¹⁰

¹Shonan Kamakura General Hospital, Kamakura, Japan ²Kokura Memorial Hospital, Kitakyushu, Fukuoka, Japan ³Saiseikai Yokohama-City Eastern Hospital, Yokohama City, Kanagawa, Japan ⁴Japan Labour Health and Welfare Organization Kanto Rosai Hospital, Kawasaki, Kanagawa, Japan ⁵Japan Labour Health and Welfare Organization Kumamoto Rosai Hospital, Yatsushiro, Kumamoto, Japan ⁶Hokkaido Social Insurance Hospital, Sapporo, Hokkaido, Japan ⁷The Cardiovascular Institute Hospital, Minato, Tokyo, Japan ⁸Kyoto-Katsura Hospital, Kyoto, Japan ⁹Boston Scientific Corporation, Maple Grove, MN; ¹⁰Boston Scientific Corporation, Marlborough, MA

Background: Small vessel diameter is associated with increased restenosis rates and adverse outcomes following coronary stenting. The PLATINUM Japan Small Vessel multicenter study specifically assessed small vessel stenting in Japanese patients treated with the PROMUS Element everolimus-eluting stent (Boston Scientific, Natick, MA). Follow-up beyond 1 year has not been reported previously.

Methods: Patients with a single de novo target lesion ≤ 28 mm long and ≥ 2.25 to <2.50 mm in diameter were eligible for treatment with a 2.25 mm diameter PROMUS Element stent.

Results: A total of 60 patients were enrolled at 14 clinical sites; 32 patients were randomized to receive routine angiography following the 1-year clinical follow-up (angiography was completed in 29 patients). Patients were 69.2 ± 9.8 years of age, 68.3% male, and 36.7% had medically treated diabetes. Average baseline reference vessel diameter was 2.02 ± 0.26 mm. Technical success and procedural success were both 100% (60/60). Post-dilation was used in 70.0% with a 16.6 atm average pressure. Dual antiplatelet treatment was used in 78.3% of patients at 2 years post-procedure. Two-year clinical follow-up is complete in 100% of patients. Through 365 days post-procedure, there were no major adverse cardiac events. In-stent late loss was 0.18 ± 0.30 mm in the angiographic subset. Following angiographic assessments (366-396 days post-procedure) target lesion revascularization (TLR) occurred in 2 patients (including 1 patient in the angiographic subset); there were no additional TLRs through the 2-year follow-up. Target vessel revascularization outside the target lesion occurred in 3 patients through the 2-year follow-up. One patient (1.7%) experienced a non-Q-wave myocardial infarction (MI) in the target vessel 413 days post-procedure. There were no Q-wave MIs or stent thromboses through 2 years.

Conclusion: The results support the safety and efficacy of the PROMUS Element 2.25 mm stent in Japanese patients.

CRT-48

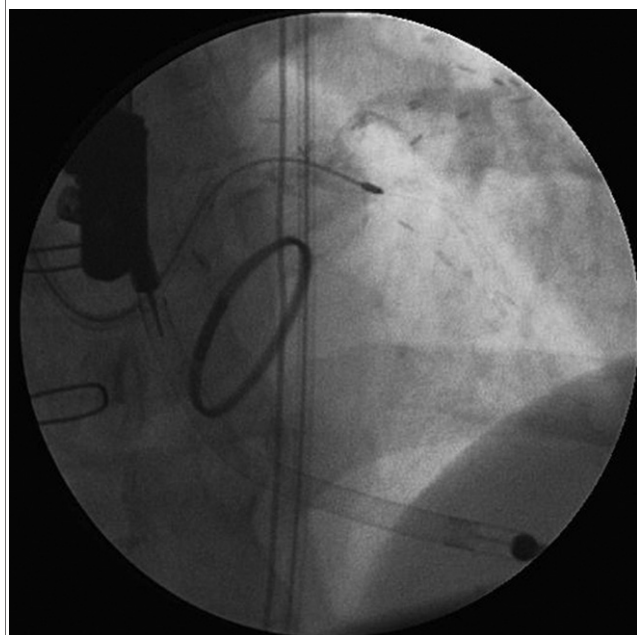
Drug Eluting Balloon for De-Novo, In stent Restenosis and Bifurcation Lesions of Coronary Artery Disease: Short and Intermediate Results, Prospective Registry

Saad Mohamed Al Kasab, Menwar Mutared Al Anazi, Ali AlMasood, Mohammed AlKasab, Rida Nourallah
Prince Sultan Cardiac Center, Riyadh, Saudi Arabia

Objectives: This prospective study designed to assess the safety and short and intermediate term efficacy of drug eluting balloon (DEB) in the treatment of de-novo, in-stent restenosis and bifurcation coronary artery disease (CAD) in Saudi Arabic Population.

Methods: Total of 64 patients so far enrolled in a prospective registry using a Be Brown Paclitaxel-coated balloon (DEB) at our hospital, 61 patients were studied for short and intermediate term outcomes (6 to 12 months). All patients with symptomatic CAD requiring percutaneous intervention (PCI) with DEB were included. Clinical follow-up was conducted at 6 to 12 months. Coronary angiography (CAG) or SPECT Scan were done in 70% of patients during this period. Primary outcome was a composite of target vessel revascularization and mortality.

Results: Procedural success was achieved in 96% of the patients. Two patients were failed due to failed DEB to cross heavily calcified vessel. Mean age was 60.8 ± 30 years. 47 patients (77%) presented with stable angina and 9 patients 15% with acute coronary



CRT-46

Long term Outcomes of Patients Treated With The Paclitaxel- Versus The Everolimus -eluting Stents in a Consecutive Cohort of Patients at a Tertiary Medical Center

Nicolas W Shammas, Gail A Shammas, Elie Nader, Michael Jerin, Luay Mrad, Nicholas Ebbecke, Wabeb J Shammas, Alexander Hafez, Ryan Kelly, Emily Reynolds
Midwest Cardiovascular Research Foundation, Davenport, IA

Background: In this study we compare the outcomes of the paclitaxel-eluting stent (PES) versus the everolimus-eluting stent (EES) treated patients at a tertiary medical center and up to two years follow up.

Methods: Unselected consecutive patients were retrospectively recruited following stenting with PES (159 patients) or EES (189 patients). The first 100 consecutive patients in each cohort underwent syntax scoring. The primary endpoint of the study was target lesion failure (TLF) defined as the combined endpoint of cardiac death, non fatal myocardial infarction or target lesion revascularization (TLR). Secondary endpoints included target vessel revascularization (TVR), target lesion revascularization (TLR), target vessel failure (TVF), acute stent thrombosis (ST), total death, cardiac death, and non fatal myocardial infarction (MI). Analysis was performed with patient number as the denominator.

Results: The syntax scores in the 2 groups were similar (20.3 ± 13.9 vs 20.4 ± 13.8 , $p=0.97$). Patients treated with the PES stent had less congestive heart failure and restenotic lesions, but a higher prevalence of longer lesions, non left main bifurcations, and required more stents per patient (4.3 ± 2.8 vs. 2.9 ± 2.1). The primary unadjusted outcome of TLF occurred in 29.3% PES vs 20.3% EES ($p=0.059$). The secondary unadjusted endpoints for PES vs EES respectively were: TVF 36.7% vs 28.0% ($p=0.106$), TVR 35.7% vs 26.5% ($p=0.079$), definite and probable ST 1.2% vs 1.6%, non fatal MI 4.5% vs. 4.2%, and cardiac mortality 5.6% vs 3.2%. A propensity matched analysis showed no significant difference in the primary endpoint of TLF ($28.6\% \pm 16$ vs $24.6\% \pm 14$, $p=0.67$) in PES vs EES respectively.

Conclusion: Using unadjusted analysis, EES had lower TLF than PES in a broad cohort of patients and lesions undergoing PCI. However, when baseline differences between the 2 cohorts were adjusted for, similar efficacy between the PES and EES was seen at 2 years follow-up.

syndrome (ACS). 25 patients (41%) had triple vessel CAD. Sixty percent were classified as having ACC/AHA B-2 or type coronary arteries including bailout stenting post DEB required in 8 patients %.

Immediate result mean diameter stenosis was $80\% \pm 8$ decrease to $5\% \pm 9$ post DEB dilatation and the diameter stenosis reached $15\% \pm 20$ with coronary angiography follow up at 6 to 12 months. 7 patients (11%) have restenosis (5 patients have PCI and 2 patients have CABG). 37 patients (59%) who were followed by either re-cath (17 patients) or SPECT Scan (20 patients) showed no evidence of restenosis. The remaining 17 patients (30 %) were followed clinically and showed no Angina. One patient died from cancer one month after PCI. Two patients failed because of inability to cross the lesion. There was no cerebrovascular accident and no major bleeding.

Conclusion: Be Brown Pacilitaxel-coated balloon (DEB) can be used safely with good and successful intermediate result with target vessel restenosis of 7 patients (11.3) % and non cardiac mortality of 1.6%.

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CRT-49

ABSTRACT WITHDRAWN

Left Main Intervention

CRT-50

Predictors of In-hospital Outcome after Primary PCI of Left Main Coronary Artery Acute Myocardial Infarction with Cardiogenic Shock

Koushi Matsuo, Yasunori Ueda
Osaka Police Hospital, Osaka, Japan

Background: In patients with acute myocardial infarction (AMI) and cardiogenic shock, emergency revascularization improves long-time survival. However, predictors of in-hospital outcome after primary PCI of left main coronary artery (LMCA) AMI remain unclear.

Methods: Consecutive 19 patients admitted to our hospital presenting Killip IV heart failure and occluded LMCA on emergent coronary angiogram were enrolled. We performed primary PCI of LMCA.

Patients' clinical background, angiographic findings, results of primary PCI, laboratory data, usage of circulatory supporting devices (IABP and PCPS), and elapsed time (from onset to reperfusion) were retrospectively examined. Patients who died in hospital and those who survived were compared.

Results: Successful reperfusion was achieved in 19 (100%) patients; IABP was used in 19 (100%) but PCPS in 6 (32%) patients; and 13 (68%) patients survived but 6 (32%) patients died in hospital. Prevalence of diabetes mellitus (83% vs. 23%; $p < 0.05$), elapsed time (5.8 ± 2.6 vs. 2.8 ± 1.0 hours; $p < 0.05$), and peak CK (15272 ± 10263 vs. 6608 ± 3612 U/l; $p < 0.05$) were larger in patients who died than in those who survived.

Conclusion: Short elapsed time, small infarct size, and non-diabetic patients were associated with good in-hospital outcome. Therefore, sooner primary PCI of LMCA should be an effective therapeutic strategy for LMCA AMI presenting cardiogenic shock.

CRT-51

Stenting of Unprotected Left Main Stem Using the Zotarolimus-coated Endeavor™-Stent. A Single Center Registry

Klaus Hertting, Angelika Lorenz, Daniel Hausmann, Claudia Zeiler, Werner Raut
Buchholz Hospital, Buchholz, Germany

Background: The aim of this registry is to demonstrate whether the implantation of a Zotarolimus-eluting (ZES) Endeavor™ stent (Medtronic Corp., USA.) into an unprotected left main stem is both safe and efficiently feasible in the long term, in an unselected patient population with significant co-morbidities.

Methods: Between February 2006 and February 2010, all patients of our department (no on-site cardiac surgery, 24 hours on-call service) who underwent stenting of an unprotected left main stem received an Endeavor™-Stent. Treatment of concomitant lesions was left to the investigators discretion. All patients were included into a registry containing both clinical and interventional data. During follow-up patients were contacted with a written questionnaire. If necessary, the information was supplemented by telephone contact with the patients or their treating physicians. Primary endpoints included death, myocardial infarction (MI) or repeated target lesion revascularization (TLR) and the combination of events (MACE).

Results: A total of 58 patients were included (42 men, 16 women, median age 72.3 years). 24% of all the patients had diabetes mellitus. In 53% of the patients, the intervention took place due to angina or proven stress ischemia, in 34% due to a MI within 72 hours, in 12% due to a myocardial infarction more than 72 hours before. Twelve percent had a severely reduced left ventricular ejection fraction ($< 30\%$), and 4 patients (7%) were in cardiogenic shock. The median logistic EuroScore was 4.4%; the SYNTAX Score 22.0. Seventy-four percent of the lesions were bifurcation lesions. In 53% of cases there was no intervention of other lesion during the index procedure, in 21% only with Endeavor™ stents, in 16% only with bare metal stents (BMS), in 10% both with Endeavor™ stents and BMS. The median follow-up time was 34.7 months. After 12, 24 and 36 months, total mortality was 14, 17 and 22%; cardiac mortality was 2, 4 and 9%; the TLR rate was 6, 6 and 8%; and the MACE rate was 21, 24, 30 and 33%. Seventy-one percent of all patients had dual antiplatelet therapy up to 6 months after the procedure. Confirmed stent thrombosis occurred in only one case during the follow-up period.

Conclusions: As our registry represents all-comers data, the long-term results concerning the safety and efficiency of the Endeavor™ stent in the unprotected main stem of the left coronary artery appeared acceptable.

CRT-52

Impact Of Vascular Access Route In Left Main Stem (LMS) Intervention

Ashish Shah, Tim Kinnaird, Ashesh N Buch, Nick Ossei-Gerning, Richard Anderson
University Hospital of Wales, Cardiff, United Kingdom

Background: Percutaneous coronary intervention (PCI) using radial arterial access is challenging and requires steep learning curve, but it is associated with significantly reduced morbidity and mortality, mainly due to reduced procedure related bleeding complications. PCI for left main stem (LMS) coronary artery disease is increasing over period of time.

Methods: We analyzed catheter laboratory data from University Hospital of Wales, Cardiff, UK from 2006 to 2010, assessing number of patients undergoing PCI to LMS with or without other vessel coronary intervention using different arterial access (radial vs. femoral arterial route) and procedure outcome.

Results: Total 4972 PCIs were performed, of which 177 patients underwent PCI to LMS. Radial access was used in 109 patients, whereas femoral access was used in 68 patients. Their subject characteristics were similar. Patients with previous history of CABG required using left radial access.

During the procedures through radial or femoral access number of vessels (1.9 ± 0.1 vs. 2.2 ± 0.2) or lesions (2.4 ± 0.2 vs. 2.5 ± 0.1) intervened, as well as number of stents (1.9 ± 0.2 vs. 2.3 ± 0.2) used through both accesses were similar. There was no significant difference in procedure time, amount of contrast or radiation use in these groups. We used 7F system through radial access in 18 of our patients (6F system in rest of the patients). Immediate (in hospital) procedure related complications were low using radial vs. femoral access (coronary dissection: 2.8 vs. 3.2%; bleeding: 0.9 vs. 7.8% and shock 2.8 vs. 4.7%). Only 2 patients (1.8%) required changing of the vascular access from radial to femoral due to difficult vascular anatomy.

Proportion of patients undergoing PCI to LMS using radial access (than femoral access) has significantly increased over last 5 years in our institute.